

**REMARKS**

Claims 2-4 have been amended. No new matter has been added. Support for the amendments can be found throughout the original specification and specifically on pages 7-11 of the original specification. Claims 1-6 are presented for further examination.

**Election/Restriction**

Claims 5 and 6 have been withdrawn from consideration as being directed to non-elected inventions. Applicants respectfully request rejoinder of the method claims 5 and 6 upon allowance of composition claims 1-4.

**Non-statutory Double Patenting Rejection**

Claims 1-4 stand rejected under a non-statutory obviousness-type double patenting based on claims 5 and 11 of U.S. Patent No. 6,132,733.

Claims 1-4 stand rejected under a non-statutory obviousness-type double patenting based on claims 1-4 of U.S. Patent No. 5,453,273.

While Applicants respectfully disagree with the propriety of these rejections, in the interests of expedited examination Applicants have filed concurrently herewith a terminal disclaimer with respect to each prior issued

patent. Accordingly, Applicants respectfully request the withdrawal of the double patenting rejections.

**35 U.S.C. § 112, 2<sup>nd</sup> Rejection**

Claims 1-4 stand rejected under 35 U.S.C. 112, 2<sup>nd</sup> as being indefinite.

The Office finds the language “effective amount” to be vague and indefinite. Specifically, the Office’s position is that it is unclear what amount is encompassed by the limitation. The Office also finds that it is unclear to what “effective” applies against.

Applicants respectfully disagree with the propriety of this rejection. Applicants believe that it is clear “effective amount” means that the amount of dermatophyte culture in the vaccine must be at least the amount that is required to provide increased immunity against ringworm infection caused by this dermatophyte. Moreover, the instant specification provides a concrete example of at least one effective amount at pages 7-11. Accordingly, Applicants believe that one of ordinary skill in the art would be able to readily determine the amount of the culture needed in order to make it effective as a vaccine. Additionally, the public is provided with clear notice as to the metes and bounds of the claimed invention since if the amount of killed pure culture used in a potentially infringing product results in a composition that when administered to an animal fails to provide any increased immunity to ringworm, then that product *would not* infringe the present claims. However, if the composition does

provide increased immunity to ringworm, then the composition *would* infringe the instant claims.

“‘[E]ffective amount’ is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation.” *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F. 3d, 1373, 1383-84 (Fed. Cir. 2003), quoting *In re Halleck*, 422 F. 2d 911, 914 (C.C.P.A. 1970).

One of ordinary skill in the art could determine the specific amount of the dermatophyte culture needed to be added to a carrier in order to render the composition effective as a vaccine, without undue experimentation. As such, the claims are clear and definite. Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

### **CONCLUSION**

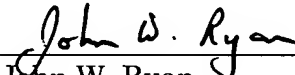
Applicants believe the present paper to be a complete and thorough response to the Non-Final Office Action. In view of the foregoing amendments and remarks, the application is respectfully submitted to be in condition for allowance. Accordingly, a timely favorable action is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #101919.56851C3).

Respectfully submitted,

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